REMARKS/ARGUMENTS

Upon entry of this Amendment, Claims 1 and 4-10 will be pending in the application.

Claim 1 has been amended to more clearly recite a method of treating an Alzheimer's patient, wherein the method comprises administering a daily dosage of from 100 mg to less than 1,000 mg of hypoxanthine, xanthine and/or inosine to the patient. Basis for the amended claim language is provided in the specification, for example, at page 3, paragraph [00013].

Claims 2 and 3 have been canceled.

Claim 4 has been amended to more clearly recite that the daily dosage further comprises an antioxidant.

Newly added Claim 6, which depends from Claim 4, recites that the antioxidant comprises a polyphenol. Basis for the language of Claim 6 is provided in the specification, for example, at page 5, paragraph [00016].

Newly added Claim 7, which depends from Claim 4, recites that the antioxidant comprises vitamin C and a polyphenol. Basis for the language of Claim 7 is provided in the specification, for example, at page 5, paragraph [00017].

Newly added Claim 8, which depends from Claim 1, recites that the daily dosage comprises a maximum of 500 mg of the hypoxanthine, xanthine and/or inosine. Basis for the language of Claim 8 is provided in the specification, for example, at page 13, paragraph [00049].

Newly added Claims 9 and 10, which depend from Claim 1, recite that the daily dosage comprises hypoxanthine or inosine, respectively. Basis for the language of Claims 9 and 10 is provided in the specification, for example, at page 13, paragraph [00049].

Claims 1-5 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to provide a sufficient description of the invention. By the present Amendment, Claim 1 has been amended to more clearly recite that the daily dosage administered to the patient comprises specific compositions, namely, hypoxanthine, xanthine and/or inosine. It is submitted that the amended claims meet the requirements of 35 U.S.C. § 112, first paragraph.

Claims 1-5 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Peeters '132 in view of Howard et al. '110. According to the Office Action, Peeters '132 discloses the treatment of Alzheimer's disease with guanosine and precursors and/or derivatives thereof, including xanthosine, as well as guanine, inosine, xanthine, hypoxanthine, 5' inosinic acid, and mono-, di- and triphosphates of guanosine. The Office Action states that Peeters '132 discloses pharmaceutical compositions comprising each of the disclosed compounds. The Office Action acknowledges that Claim 1 recites that the composition contains a "daily dosage amount" of from 100 to less than 1,000 mg, but states that, properly construed at its broadest, the recitation "daily dosage amount" is merely a recitation of intended use, and the claims encompass any composition which can be administered at the claimed daily rate of administration.

Applicants respectfully traverse the Examiner's contention that the recited "daily dosage amount" is merely a recitation of intended use. The presently claimed invention is a method of treating an Alzheimer's patient, wherein the method comprises administering a daily dosage of from 100 mg to less than 1,000 mg of hypoxanthine, xanthine and/or inosine to the patient. Thus, Claim 1 does not merely recite a "daily dosage amount", but rather requires administering a specified amount of hypoxanthine, xanthine and/or inosine to an Alzheimer's patient on a daily basis.

The Office Action further states that Peeters '132 discloses that xanthosine should be administered at dosages of from 20 mg/kg/day to 150 mg/kg/day. According to the Office Action, assuming a 50 kg person, this dosage would result in an administration of compositions of 1 to 7.5 grams per day. The Office Action states that one of ordinary skill in the art would have recognized that a suitable method of administering 1 gram of xanthosine, or more, per day would have been by administering in 500 mg oral dosage forms. The Examiner takes official notice of the fact that the determination of suitable dosage regimen for the therapeutic methods in Peeters '132, including the use of 500 mg dosage forms, was clearly within the purview of the artisan of ordinary skill at the time of Applicants' invention. The Office Action further states that the claims are obvious absent some demonstration of an unexpected result coming from the claimed use of dosage forms containing less than 1 gram, or no more than 500 mg of xanthosine.

Applicants respectfully submit that Peeters '132 does not raise a *prima facie* case of obviousness of the presently claimed invention because those skilled in the art, reading the relatively high levels of uric acid precursors required to be administered by Peeters '132, would not be led to treat an Alzheimer's patient with less than 1,000 mg of hypoxanthine, xanthine and/or inosine per day, as presently claimed. Peeters '132 teaches that significantly higher levels of uric acid precursors must be administered in order to be effective. Accordingly, Peeters '132 does not render Claim 1 *prima facie* obvious.

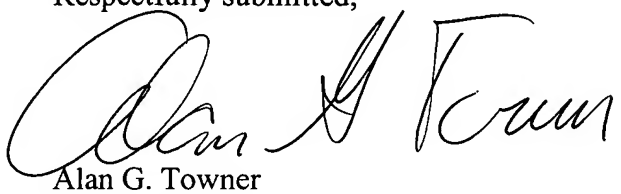
As to dependent Claims 4 and 5, the Office Action acknowledges that Peeters '132 differs from the claimed invention in that the reference does not disclose the inclusion of the elected additional ingredient vitamin C in the disclosed compositions. The Office Action relies upon Howard et al. '110 as a teaching that vitamin C should be included in a regimen of treating Alzheimer's. According to the Office Action, one of ordinary skill in the art, reasonably expecting the vitamin C of Howard et al. '110 to be beneficial in Peeters' method of treating Alzheimer's, clearly would have been motivated to have included Howard et al.'s vitamin C in the therapeutic regime disclosed by Peeters '132. The Examiner notes that it is well know that it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose.

Howard et al. '110 does not remedy the above-noted deficiencies of Peeters '132. Even if the teachings of Peeters '132 and Howard et al. '110 could properly be combined, such a combination would not render the present claims *prima facie* obvious because the prior art does not provide a teaching, suggestion or motivation to treat an Alzheimer's patient by administering a daily dosage of less than 1,000 mg of hypoxanthine, xanthine and/or inosine, as recited in Claim 1.

In view of the foregoing amendments and remarks, it is submitted that Claims 1 and 4-10 meet the requirements of 35 U.S.C. § 112 and are patentable over the prior art of record. Accordingly, an early notice of allowance of this application is respectfully requested.

In the event that any outstanding matters remain in connection with this application, the Examiner is invited to telephone the undersigned at (412) 263-4340 to discuss such matters.

Respectfully submitted,



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